



The LEWIN GROUP

Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients – An Update

Report Prepared for:

Transplant Pharmacy Coalition

Prepared by:

The Lewin Group, Inc.

April 15, 2007

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Prepared by:
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EXECUTIVE SUMMARY

The Medicare Prescription Drug, Improvement and Modernization Act (MMA) was implemented in January 2005. The MMA requires CMS to pay specialty pharmacy providers a “pharmacy supply fee” to cover the administrative and other costs associated with dispensing immunosuppressive drugs and providing associated professional services to Medicare transplant patients. Professional services include focused therapeutic management, patient counseling, and assistance with the paperwork associated with insurance reimbursement. MMA also mandated a change to an average sales price (ASP) based payment system for Medicare Part B drugs.

Successful immunosuppressant therapy has two requirements: first, that the treatment be fine-tuned to each individual patient in terms of drugs selected, dosages, and side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. The second requirement is that transplant recipients take their medications as prescribed, and promptly report any complications or adverse reactions to their doctors in order that dosages can be corrected over time. These two aspects make immunosuppressant therapy a challenge, especially in the initial months after the transplant, and require sustained and careful attention from the specialty pharmacy staff.

The literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug regimens.^{1,2,3} Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.⁴

This finding underscores the importance of the specialty pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.⁵ A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages vs. a 65% adherence rate found in the literature.⁶ Using decision analysis methods, the

¹ Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

² Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.

³ Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. *Transplant International* 18: 1121-1133.

⁴ Vlaminc H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

⁵ Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. *Jour Transplant Coordination* 9(1): 13-16.

⁶ Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence*. Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

authors estimated a potential cost savings of \$4,150 per patient per year associated with increased adherence. Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, there is a compelling need for public policy to support providers' efforts to help these patients adhere to their medication regimens.

The Transplant Pharmacy Coalition commissioned The Lewin Group to update its 2004 analysis of the pharmacy costs associated with providing immunosuppressive drugs under Part B. Eight specialty pharmacies comprise the Transplant Pharmacy Coalition, whose members collectively fill more than 28,000 immunosuppressive prescriptions monthly and hold about 40% of the Medicare Part B market share in immunosuppressive drug dispensing.

As in 2004, The Lewin Group surveyed Coalition members for costs associated with providing immunosuppressive drugs and related pharmacy services in general and also to Medicare beneficiaries. The purpose of this report is to present our findings, comparing them to our 2004 findings where appropriate. We found that:

- Transplant pharmacies' average supply cost per immunosuppressive drug prescription has remained relatively stable between 2004 and 2007. In 2007, it is \$30.73, down slightly from \$32.62 in 2004. (These results are for those six pharmacies that participated both in 2004 and 2007.) The stability of our results suggests that our surveys have been working as intended and show a high level of reliability.
- Unlike retail chain pharmacies, transplant pharmacies routinely provide immunosuppressive drugs covered under Medicare Part B, as well as other direct services to encourage patient adherence to their drug regimen. Together with additional labor-intensive Medicare Part B requirements for documentation, pharmacies' personnel requirements are sizeable. We found that personnel costs have risen from 21.6% to 28.1% of supply costs (excluding the cost of goods sold) between 2004 and 2007. Personnel costs rose from \$7.04 in 2004 to \$8.65 in 2007.
- Although Centers for Medicare and Medicaid Services (CMS) eliminated the requirement for the submission of the Durable Medical Equipment Regional Centers Information Forms (DIFs) to receive reimbursement for immunosuppressive drugs, administrative costs for filing Medicare claims still account for a sizeable amount of the pharmacies' supply cost. We found these administrative costs to be approximately 23.2%, up from 19.7% in 2004, from \$6.43 to \$7.13. This is contrary to CMS' expectation.
- Unlike other prescription drug payers, Medicare does not provide real-time online adjudication of claims, making coordination of benefits with secondary insurers costly and sometimes impossible. Several pharmacies noted that Medicare denials have increased since 2004, resulting in additional work and expense for the pharmacy to resubmit the claim and file an appeal. This observation was confirmed by the survey which found that administrative overhead has increased to 13.4% from 9.0% in 2004. Administrative overhead increased from \$2.93 in 2004 to \$4.13 in 2007.
- In contrast, other non-labor costs declined from 6.4% in 2004 to 1.2% in 2007, or from \$2.08 to \$0.37. Shipping declined from 14.8% in 2004 to 11.5% in 2007, or from \$4.82 to \$3.55. Inventory cost declined from 11.8% in 2004 to 1.7% in 2007, or from \$3.84 to \$0.52.

Exhibit 1 below presents a summary of the 2007 survey results, as compared to the results from 2004. The ratio of average pharmacy supply costs to average total costs decreased from 8.0% to 7.0%, reflecting both a higher cost of goods and somewhat lower supply costs. The average per prescription cost declined from \$32.62 in 2004 to \$30.73 in 2007. The amount of the supply costs devoted to filing Medicare claims rose from \$8.86 in 2004 to \$9.40 in 2007.

Exhibit 1 Summary Results

	2004 Survey ^{a/}	2007 Survey
Ratio of Average Supply Costs to Average Total Costs	8.0%	7.0%
Average per-Prescription Supply Cost	\$32.62	\$30.73
Amount Attributable to Additional Cost for Filing Medicare Claims	\$8.86	\$9.40

a/ Reanalysis of 2004 survey using data from the six pharmacies that responded to the 2007 survey and 2007 data categories. The 2007 survey collected FY 2006 data.

Source: Lewin Group analysis of survey data.

INTRODUCTION

The Transplant Pharmacy Coalition is comprised of eight specialty pharmacies who serve approximately 40% of the Medicare immunosuppressive market. The remainder of the market is served by retail pharmacy chains, hospital outpatient pharmacies at transplant centers, and Pharmacy Benefit Managers (PBMs) [which do not typically serve Medicare patients due to the high cost of filing Medicare claims].

The Transplant Pharmacy Coalition commissioned the Lewin Group to update its 2004 study of transplant pharmacy costs for providing immunosuppressive drugs to Medicare beneficiaries. We collected FY 2006 cost data from coalition members, and also conducted a focused review of the research literature on transplant patient adherence to immunosuppressive therapy. Because transplantation is the preferred treatment for end-stage renal disease (ESRD) and is less expensive than dialysis, the preservation of functioning kidney transplants has been considered to be a national priority.⁷ Medication non-adherence is a leading barrier to continued transplant function, so we conducted a focused review of what is currently known about the topic.

In this introduction, we present the study purpose, study rationale, and a discussion of the services provided by specialty transplant pharmacies.

Study Purpose

The study purpose was threefold:

- To identify the supply costs associated with providing pharmacy services to Medicare Part B transplant recipients;
- To approximate average total and component clinical administrative costs of providing these services; and
- To develop average per prescription pharmacy supply cost estimates under the payment methodology outlined by the *Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)*.

Study Rationale

Transplantation represents a solution to many kinds of end-stage disease. However, without immunosuppressive drug therapy, transplant recipients experience organ rejection, meaning that the body's immune system attacks the donor organ's cells, reacting to them as if they were harmful.⁸ Medications that curb the immune system (called immunosuppressant drugs) are

⁷ Dobson A, DaVanzo J, Kerns J. (2000). Appendix E. Cost estimates for expanded Medicare benefits: skin cancer screening, Medically necessary dental services, and immunosuppressive therapy for transplant recipients. In: Field MJ, Lawrence RL, Zwanziger L (eds). *Extending Medicare Coverage for Preventive and Other Services*. Institute of Medicine. Washington D.C.: National Academy Press:347-362.

⁸ Kreis HA, Ponticelli C. (2001). Causes of late renal allograft loss: chronic allograft dysfunction, death, and other factors. *Transplantation* 71: S55.

essential for transplant recipients. The discovery of immunosuppressant drugs – and the advances still being made – allow many transplant recipients to live longer, healthier lives.⁹

Nevertheless, immunosuppression creates a new set of problems. People with suppressed immune systems are less likely to reject their transplanted organs, but also less able to fight off harmful "invaders." This leaves them vulnerable to infections and some types of cancer. Immunosuppressive drugs (also called "anti-rejection drugs") can also cause other side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. Finally, immunosuppressant medications can be costly.¹⁰

The rapidly increasing growth of organ transplantation has resulted in a dramatic increase in the number of immunosuppressive agents and other medications used in transplantation, resulting in more complex medication regimens and greater potential for interactions, adverse effects and increased costs. However, despite advances in immunosuppressive therapy, a major weakness in the "therapeutic chain" remains the patient's behavior.¹¹

Pharmacists and other staff at specialty transplant pharmacies often work closely with each patient to provide specialized therapeutic management, medication distribution, and counseling. An early study demonstrated that patients' knowledge about anti-rejection medications increased from 53% to 75% after counseling by pharmacists. Their knowledge level about other drugs such as antimicrobial and antihypertensive agents was 15% before pharmacist counseling and increased to 50% to 60% following counseling.¹²

Transplant centers typically have outpatient pharmacies that provide many of these services to patients. However, a large percentage of patients live too far from transplant centers to use them on a regular basis.

Retail chain pharmacies typically do not supply immunosuppressive drugs due to:

- The small number of transplant patients relative to population;
- The high cost of inventory and high risk of waste from drug expiration (due to the high cost of drugs and small number of patients); and
- Lack of business desire to deal with complex Medicare claims procedures.

Mail-order PBM pharmacies typically do not serve Medicare Part B transplant patients, as most mail-order pharmacies do not have processes in place to file Medicare claims. Therefore, specialty transplant pharmacies are the only practical option for many patients, especially Medicare Part B patients.

⁹ Pascual M, Theruvath T, Kawai T et al. (2002). Strategies to improve long term outcomes after renal transplantation. *N Eng J Med* 346:580.

¹⁰ Yen EF, Hardinger K, Brennan D et al. (2004). Cost-effectiveness of extending Medicare coverage of immunosuppressive medications to the life of a kidney transplant. *Am J Transplant* 4: 1703-1708.

¹¹ Michelon TF, Piovesan F, Castilho C et al. (2002). Noncompliance as a cause of renal graft loss. *Transplant Proc* 34:2768-2770.

¹² De Geest S, Borgermans L, Gemoets H, et al. (1995) Incidence, determinants, and consequences of subclinical non compliance with immunosuppressive therapy in renal transplant recipients. *Transplantation* 59:340-347.

Transplant Pharmacy Practices that Increase Supply Costs of Dispensing

Transplant pharmacy practice differs from that of retail pharmacies in several ways, all of which increase costs. The transplant pharmacy service model involves the provision of many specialized services. For example, the initial prescriptions are often hand-delivered to the hospital on the day of discharge. Until the correct dosage for the patient is determined (approximately four months), the pharmacist works closely with the prescribing doctor to determine the correct dosage, and with the patient to monitor for symptoms of incorrect dosage or side effects.

Transplant pharmacies not only accept Medicare patients, they file Medicare claims. The filing of Medicare claims is more difficult and more costly than filing other types of claims.

Non-Medicare payers – both private insurers and Medicaid – offer and require instant online adjudication of claims at the time a prescription is filled. Pharmacies know before delivering the product how much they will be paid and how much of a co-payment to collect. Medicare Part B does not utilize the online adjudication system. This increases billing errors and makes coordination of benefits with secondary insurers difficult and sometimes impossible. Medicare often errs in identifying patients as having “primary” or “secondary” Medicare coverage. Prior to filing a claim, pharmacies can call Medicare to determine this status, but the answers are often incorrect.

Medicare claims add substantial costs due to a complicated filing process and the increased cost of coordinating benefits without the presence of an instant adjudication process. In addition, Medicare often provides inaccurate information about patient coverage status (primary vs. secondary), and secondary reimbursement is often lost due to Medicare errors discovered after date of service.

Successful immunosuppressant therapy has two requirements: first, that the treatment be fine-tuned to each individual patient in terms of drugs selected, dosages, and side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. The second requirement is that transplant recipients take their medications as prescribed, and promptly report any complications or adverse reactions to their doctors. These two aspects make immunosuppressant therapy a challenge, especially in the initial months after the transplant, and require sustained and careful attention from the specialty pharmacy staff.

The literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug regimens.^{13,14,15} Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.¹⁶

¹³ Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

This finding underscores the importance of the transplant pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.¹⁷

A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages, vs. a 65% adherence rate obtained from the literature.¹⁸ Using decision analysis methods, the authors estimated a potential cost savings of \$4,150 per patient per year associated with increased adherence. The study also presented the annual cost of functioning grafts of \$15,537 vs. \$70,930 for failed grafts.¹⁹ Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, it seems sensible for public policy to support providers' efforts to help these patients adhere to their medication regimens.

¹⁴ Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.

¹⁵ Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. *Transplant International* 18: 1121-1133.

¹⁶ Vlaminc H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

¹⁷ Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. *Jour Transplant Coordination* 9(1): 13-16.

¹⁸ Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence*. Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

¹⁹ USRDS, 2005.

METHODOLOGY

In this section, we present an overview of our study process, and a discussion of our data analytic methods.

In 2004, Lewin developed a study process that was comprised of the following five steps. In this update study, we followed the same five steps, and performed a targeted review of the literature on non-adherence with immunosuppressive medications. As in 2004, we worked closely with the Transplant Pharmacy Coalition to verify study objectives.

1. In the earlier study, we worked with the Transplant Pharmacy Coalition to identify pharmacy supply cost categories and to develop a survey instrument. In this study, we verified the 2004 cost categories with the pharmacies, updating our instrument where needed.
2. We collected cost accounting data from participating transplant pharmacies using the updated instrument. Cost data were allocated to the Medicare Part B transplant line of business using the same top-down approach that was used in 2004.
3. We reviewed data with each participant to ensure their accuracy.
4. We analyzed the survey data, and presented draft study results for review.
5. We then drafted and finalized the report.

Data Collection

Data were collected from six of the eight specialty pharmacies of various sizes providing wide geographic coverage. As part of the earlier survey development, The Lewin Group and the Transplant Pharmacy Coalition identified and defined cost categories. The prior survey was used for this update study. For this study, we verified that the cost categories were still being created in the same way as in 2004. Where categories had changed for one company, we asked that costs in the new category be allocated to the original 2004 categories. Six transplant pharmacies completed the survey, providing FY2006 cost information. As before, to ensure consistency of reporting and accuracy of cost data, we worked individually with each company.

The current survey collected cost data on:

- Number of Medicare and non-Medicare prescriptions filled
- Cost of goods sold
- Clinical and administrative costs
- Inventory and overhead costs
- Cost of processing Medicare claims
- Medicare bad debt and collection costs

The 2007 survey instrument can be found in **Appendix A**.

Analytic Methods

Cost estimates were made with the intent of accurately representing the transplant pharmacy industry as a whole, given our sample of six specialty pharmacies. **Average cost per prescription** was calculated for each company and then a weighted average was calculated according to the number of prescriptions (not by dollar volume).

Data were used to analyze the major cost components associated with providing immunosuppressive drugs to patients. The **percent of total cost** for each component was also calculated. Cost components include:

- Cost of Goods Sold
- Pharmacy Supply Costs
 - Pharmacy personnel
 - Medicare Part B claims processing
 - Inventory cost and inventory shrinkage*
 - Shipping
 - Rent
 - Sales and marketing
 - Administrative overhead
- Medicare Bad Debt
 - Co-payments never made
 - Collection costs

Exhibit 2 contains the key summary variables and how they were calculated.

Exhibit 2
Key Summary Variables

Statistic	Numerator	Denominator
Ratio of Average Supply Costs to Average Total Costs	Aggregate pharmacy costs, except cost of goods sold (COGS)	Aggregate pharmacy total costs (includes COGS)
Average per-Prescription Supply Cost	Aggregate pharmacy costs, except cost of goods sold (COGS)	Number of prescriptions supplied to Medicare patients
Amount Attributable to Additional Cost for Filing Medicare Claims	Aggregate cost of submitting Medicare claims plus Medicare bad debt and collection costs	Number of prescriptions supplied to Medicare patients

(Provider data reflect CY 2006)

RESULTS

In this section, we present the key summary variables for both 2007 and 2004. This is followed by a presentation of the component cost structures, also from both 2007 and 2004.

Exhibit 3 contains the results of our analyses, as well as a comparison to our 2004 results, which have been adjusted to include the same six pharmacies that participated in the study in 2007. The ratio of average pharmacy supply costs to average total costs decreased from 8.0% to 7.0%, reflecting a higher cost of goods and somewhat lower supply costs. The average per prescription cost declined from \$32.62 in 2004 to \$30.73 in 2007. The amount of the supply costs devoted to filing Medicare claims rose from \$8.86 in 2004 to \$9.40 in 2007.

Exhibit 3
Summary Results

	2004 Survey^{a/}	2007 Survey
Ratio of Average Supply Costs to Average Total Costs	8.0%	7.0%
Average per-Prescription Supply Cost	\$32.62	\$30.73
Amount Attributable to Additional Cost for Filing Medicare Claims	\$8.86	\$9.40

a/ Reanalysis of 2004 survey using data from the six pharmacies that responded to the 2007 survey and 2007 data categories. The 2007 survey collected 2006 data.

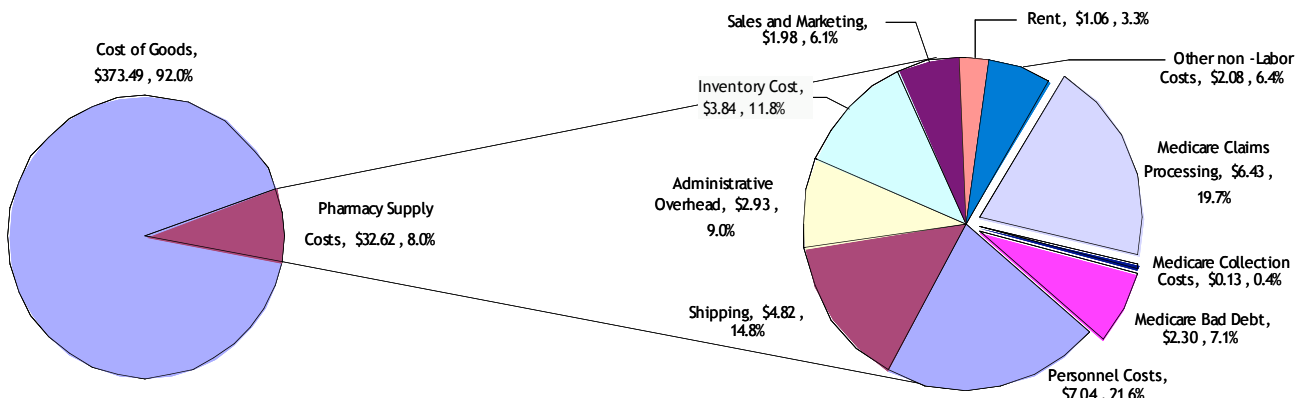
Source: Lewin Group analysis of survey data.

Exhibit 4 below contains a side by side comparison of the components of the supply cost for both 2007 and 2004.

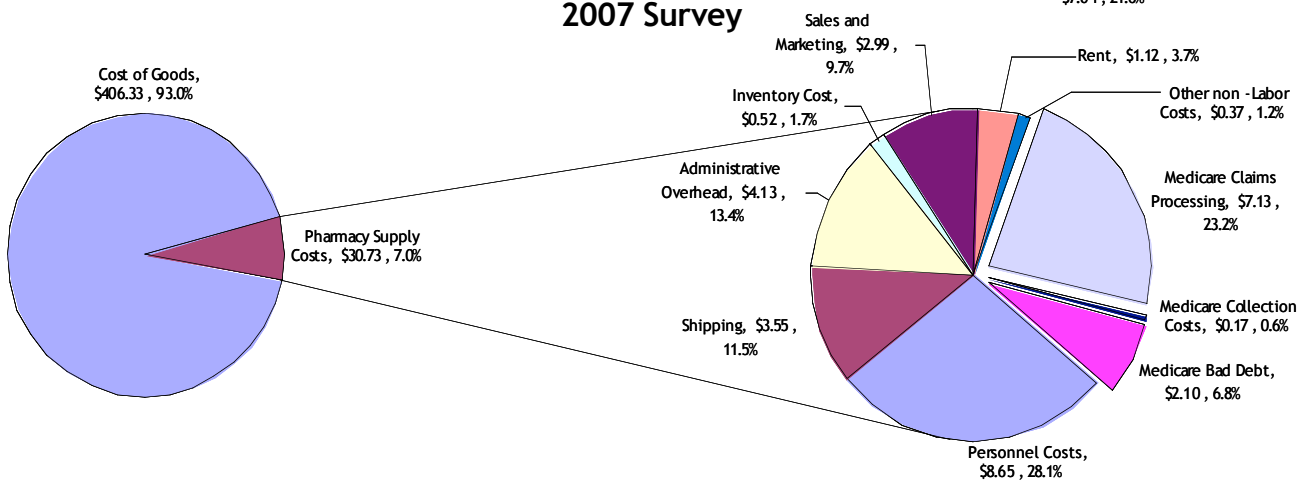
- Transplant pharmacies' average supply cost per immunosuppressive drug prescription has remained relatively stable between 2004 and 2007. In 2007, it is \$30.73, down slightly from \$32.62 in 2004. (These results are for those six pharmacies that participated both in 2004 and 2007.) The stability of our results suggests that our surveys have been working as intended and show a high level of reliability.
- Unlike retail chain pharmacies, transplant pharmacies routinely provide immunosuppressive drugs covered under Medicare Part B, as well as other direct services to encourage patient adherence to their drug regimen. Together with additional labor-intensive Medicare Part B requirements for documentation, pharmacies' personnel requirements are sizeable. We found that personnel costs have risen from 21.6% to 28.1% of supply costs (excluding the cost of goods sold) between 2004 and 2007. Personnel costs rose from \$7.04 in 2004 to \$8.65 in 2007.
- Although Centers for Medicare and Medicaid Services (CMS) eliminated the requirement for the submission of the Durable Medical Equipment Regional Centers Information Forms (DIFs) to receive reimbursement for immunosuppressive drugs, administrative costs for filing Medicare claims still account for a sizeable amount of the pharmacies' supply cost. We found these administrative costs for Medicare claims processing to be approximately 23.2%, up from 19.7% in 2004, from \$6.43 to \$7.13. This is contrary to CMS' expectation.

Exhibit 4 Comparison of 2004 and 2007 Surveys Using 2007 Cost Category Data from Respondents to Both Surveys

2004 Survey



2007 Survey



- Unlike other prescription drug payers, Medicare does not provide real-time online adjudication of claims, making coordination of benefits with secondary insurers costly and sometimes impossible. Several pharmacies noted that Medicare denials have increased since 2004, resulting in additional work and expense for the pharmacy to resubmit the claim and file an appeal. This observation was confirmed by the survey which found that administrative overhead has increased to 13.4% from 9.0% in 2004. Administrative overhead increased from \$2.93 in 2004 to \$4.13 in 2007.
- In contrast, other non-labor costs declined from 6.4% in 2004 to 1.2% in 2007 or from \$2.08 to \$0.37. Shipping declined from 14.8% in 2004 to 11.5% in 2007 or from \$4.82 to \$3.55. Inventory cost declined from 11.8% in 2004 to 1.7% in 2007 or from \$3.84 to \$0.52.
- We found that the literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug

regimens.^{20,21,22} Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.²³

- A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages vs. a 65% adherence rate found in the literature.²⁴ Using decision analysis methods, the authors estimated a potential cost savings of \$4,150 per patient per year associated with increased adherence.

²⁰ Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

²¹ Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.

²² Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. *Transplant International* 18: 1121-1133.

²³ Vlaminc H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

²⁴ Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence*. Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

CONCLUSIONS

Organ transplant is the most effective, and sometimes the only, treatment for patients with a non-functioning heart, lung, kidney, liver, pancreas, or intestine. The most common organ transplanted is the kidney (61%) for treatment of End Stage Renal Disease (ESRD).

Transplanted organs are rarely an exact match for the patient, and are therefore “rejected” by the patient's immune system.

Lifetime treatment with immunosuppressive drugs is required to suppress the patient's immune system to prevent organ rejection. Without immunosuppressive drugs supplied at the proper dosage, the patient will reject the organ and require a return to dialysis, re-transplantation or die. Successful transplantation has become inseparably linked to pharmacological immunosuppression that must be maintained for the life of the graft.²⁵

Specialty pharmacies are a dominant supplier of immunosuppressive drugs to Medicare Part B transplant patients. Together they serve about 40% of Medicare transplant patients. The Coalition's average cost of supplying a prescription to a Medicare Part B transplant patient is \$30.73, down from \$32.62 in 2004, exclusive of the cost of the drug itself (when comparing pharmacies that completed both surveys). The supply cost attributable to filing Medicare claims rose to \$9.40 from \$8.86 in 2004.

Many patients do not have reasonable access to alternative sources for these essential drugs. Continued assurance that Medicare transplant patients have access to quality service and life-sustaining drugs is an important policy objective as payment changes are considered for Medicare Part B drugs. As the cost of goods increases and supply cost pressures mount, Medicare payment policies will become ever more important to ensuring access to transplant recipients.

Our findings underscore the importance of the specialty pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.²⁶ Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, there is a compelling need for public policy to support providers' efforts to help these patients adhere to their medication regimens.

²⁵ Gaston RS. (2000). Immunosuppressive Therapy: The Scientific Basis and Clinical Practice of Immunosuppressive Therapy in the Management of Transplant Recipients. In *Extending Medicare Coverage for Preventive and Other Services* (2000). National Academy of Science, Institute of Medicine.

²⁶ Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. *Jour Transplant Coordination* 9(1): 13-16.

Appendix A: Survey Instrument

The Lewin Group

Transplant Pharmacy Coalition survey

Company Name: _____

Is your business exclusively for transplant patients?

? Yes ? No

(If Yes, columns A and B should be the same.)

Data for:

? Calendar year 2006

? Calendar year 2005

? Other period _____

	Total Pharmacy (A)	Transplant Patients (B)	Medicare Transplant Patients (C)
Number of Prescriptions			
New Prescriptions			
Refills			
Cost of Goods Sold			
Clinical Administration Costs (Personnel)			
Personnel costs, including benefits, payroll taxes, etc.			
Total cost of receiving and processing prescription orders			
Total cost of preparing orders for shipping			
Total cost of maintaining inventory (ordering, stocking, etc.)			
Total cost of processing claims			
Total cost of patient education & counseling			
Sub-total: Direct labor costs			
Clinical Administration Costs (Other)			
Total cost of shipping (UPS/FedEx/USPS/etc. bill)			
Inventory cost (Average inventory times cost of capital)			
Sub-total: Non-labor clinical administrative costs			
Administrative Overhead			
Accreditation, licensing, and permits			
Supervision			
Office supplies and other administrative expenses.			
Sales and Marketing			
Rent			
Utilities (electric, gas, heating oil, etc.)			
Insurance			
Computer hardware/software			
Telephone/Internet			
Bank charges, legal and accounting expenses			
Sub-total: Unallocated Overhead			
Medicare Bad Debt			
Include <i>only</i> Medicare copayments that were never paid. <i>Do not</i> include denied claims or non-Medicare bad debt.			
Collections costs			
TOTAL COSTS:			

If you have any questions, please contact Joan DaVanzo, (703) 269-5724.

Please return survey by e-mail or fax to:

Joan DaVanzo, E-mail: joan.davanzo@lewin.com, Fax: (703) 269-5501